

(3) *Limitations.* Milk taken from animals during treatment and for 36 hours (three milkings) following the last treatment must not be used for food. Treated animals must not be slaughtered for food use for 28 days following the last treatment. Cows with systemic clinical signs caused by mastitis should receive other appropriate therapy under the direction of a licensed veterinarian. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 58486, Nov. 2, 1993]

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

Sec.

529.50 Amikacin sulfate intrauterine solution.

529.360 Cephalothin discs.

529.365 Cephalirin sodium for intramammary infusion.

529.400 Chlorhexidine tablets and suspension.

529.810 Enflurane.

529.1003 Fluorogestone acetate-impregnated vaginal sponge.

529.1030 Formalin solution.

529.1044 Gentamicin sulfate in certain other dosage forms.

529.1044a Gentamicin sulfate intrauterine solution.

529.1044b Gentamicin sulfate solution.

529.1115 Halothane.

529.1186 Isoflurane.

529.1526 Nifurpirinol capsules.

529.2090 Salicylic acid.

529.2464 Ticarcillin powder.

529.2503 Tricaine methanesulfonate.

AUTHORITY: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

SOURCE: 40 FR 13881, Mar. 27, 1975, unless otherwise noted.

§ 529.50 Amikacin sulfate intrauterine solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 250 milligrams of amikacin (as the sulfate).

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Two grams (8 milliliters) diluted with 200 milliliters of sterile physiological saline per day for 3 consecutive days.

(2) *Indications for use.* For treating genital tract infections (endometritis, metritis, and pyometra) in mares when

caused by susceptible organisms including *E. coli*, *Pseudomonas* spp., and *Klebsiella* ssp.

(3) *Limitations.* For intrauterine infusion in the horse only. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 9640, Mar. 8, 1983, as amended at 53 FR 27852, July 25, 1988]

§ 529.360 Cephalothin discs.

(a) *Specifications.* Cephalothin discs, comply with the requirements of § 460.1 of this chapter.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The discs are used for determining the in vitro susceptibility of bacteria to cephaloridine and cephalonium.

(2) For veterinary laboratory diagnosis only.

§ 529.365 Cephalirin sodium for intramammary infusion.

(a) *Specifications.* Each 10-milliliter dose contains 200 milligrams of cephalirin sodium activity in a peanut-oil gel.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.115 of this chapter.

(d) *Conditions of use.* (1) The drug is used for the treatment of lactating cows having bovine mastitis caused by susceptible strains of *Streptococcus agalactiae* and *Staphylococcus aureus*.

(2) Administer one dose into each infected quarter immediately after the quarter has been completely milked out. Do not milk out for 12 hours. Repeat once only in 12 hours. If improvement is not noted within 48 hours after treatment, consult your veterinarian.

(3) Milk that has been taken from animals during treatment and for 96 hours (8 milkings) after the last treatment must not be used for food. Treated animals must not be slaughtered for food until 4 days after the last treatment.

[40 FR 57455, Dec. 10, 1975, as amended at 53 FR 27852, July 25, 1988]